PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-24	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP 03/05327	International filing date *(day/month/year)* 25.04.2003	Priority date *(day/month/year)* 30.04.2002
International Patent Classification (IPC) or both national classification and IPC A61J1/10		
Applicant OTSUKA PHARMACEUTICAL FACTORY, INC. et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.09.2003	29.06.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Godot, T Telephone No. +31 70 340-3319

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP 03/05327

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-25 as originally filed

Claims, Numbers

1, 3, 5-16 received on 03.12.2003 with letter of 28.11.2003

Drawings, Sheets

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,5-8,13,14
	No:	Claims	3,9-12,15,16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1,3,5-16
Industrial applicability (IA)	Yes:	Claims	1,3,5-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-4 602 910 (LARKIN MARK E) 29 July 1986 (1986-07-29)
D2: EP-A-0 639 364 (OTSUKA PHARMA CO LTD) 22 February 1995 (1995-02-22)

2. The document D1 discloses (see col. 2, line 67 to col. 4, line 55; the references in parentheses applying to this document):
A multiple-chamber medical container (10) comprising:
a container body having the chambers (*first chamber* 11, *second chamber surrounding small "container"* 34) for containing medicaments (51) therein and a partitioning seal portion (44) for separating the chambers from one another,
a medicinal outlet portion (25,26) attached to the container body for discharging the medicaments from the chambers therethrough,
and
an openable small container (34) disposed in at least one of the chambers and having a medicament (50) enclosed therein;
the partitioning seal portion (44) being openable (*sealed area* 40 *breaks after weak seal* 43 *of inner container* 34 *has been broken, see col. 4, lines 9-21)* so as to cause the chambers to communicate with one another for use,
the partitioning seal portion (44) is formed by bonding opposed inner wall surfaces (15,18) of the container body separably (*inner wall surfaces are bonded by means of walls 36,37 and weak seals 40,40 and 43*),
the sheet material (36,37) forming the small container (34) being bonded to the inner wall surfaces of the container body within the partitioning seal portion (44) (*present claim 3 !*),
the small container (34) opening in accordance with the separation of the inner wall surfaces caused by opening the partitioning seal portion (44).

Hence, the subject-matter of independent claim 3 is not new in the sense of Article 33(2) PCT.

3. The subject-matter of claim 1 differs from the subject-matter of claim 3 and therefore from the disclosure of D1, only in that the sheet material forming the small container is bonded to the opposed inner wall surfaces of the container body in the vicinity of the partitioning seal portion.
However, this difference cannot be considered to involve an inventive step because it is generally known to the person skilled in the art that the feature of binding the small container in the vicinity of the seal portion is an equivalent to the feature of binding the small container within the seal portion of document D1 and can be interchanged with that feature where circumstances make it desirable.

4. Claim 16 is considered as an independent claim because it specifies only a bag which is *suitable for* enclosing a multiple-chamber container. Such a bag is known from D1 (see col. 3, lines 60-66), or from D2 where it encloses a folded multi-chamber container (see col. 11, line 55 to col. 12, line 3).
The subject-matter of independent claim 16 is therefore not new in the sense of Article 33(2) PCT.

5. Dependent claims 5-15 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step. See for example:
D1, col. 2, line 67 to col. 4, line 61 for claims 5-12,15.
By changing the position of the medicinal outlet portion, claim 13 discloses only an obvious alternative of the embodiment disclosed in D1 and D2.
In claim 14, the wording "discharge-control seal portion" is so vague that it could correspond to a tab which is placed in the outlet port between the outlet portion and the chamber. Such a tab is well known in the field of medical containers and the skilled person would regard as a normal option to include a tab in the container described in document D1.

CLAIMS

1. (Amended) A multiple-chamber medical container comprising:

a container body having the chambers for containing medicaments therein and a partitioning seal portion for separating the chambers from one another,

a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and

an openable small container formed with sheet material disposed in at least one of the chambers and having a medicament enclosed therein;

the partitioning seal portion being openable so as to cause the chambers to communicate with one another for use,

the partitioning seal portion being formed by bonding opposed inner wall surfaces of the container body separably,

the sheet material forming the small container being bonded to the opposed inner wall surfaces of the container body in the vicinity of the partitioning seal portion,

the small container opening in accordance with the separation of the inner wall surfaces caused by opening the partitioning seal portion.

2. (Cancelled)

3. (Amended) A multiple-chamber medical container comprising:

a container body having the chambers for containing medicaments therein and a partitioning seal portion for separating the chambers from one another,

a medicinal outlet portion attached to the container body for discharging the medicaments from the chambers therethrough, and

an openable small container formed with sheet material disposed in at least one of the chambers and having a medicament enclosed therein;

the partitioning seal portion being openable so as to cause the chambers to communicate with one another for use,

the partitioning seal portion being formed by bonding opposed inner wall surfaces of the container body separably,

the sheet material forming the small container being bonded to the inner wall surfaces within the partition seal portion, and

the small container opening in accordance with the separation of the inner wall surfaces caused by opening the partitioning seal portion.

4. (Cancelled)

5. (Amended) A multiple-chamber medical container according to claim 1, wherein the distance between the small container and the partitioning seal portion is 0 to 50 mm.

6. (Amended) A multiple-chamber medical container according to claim 1 wherein,

the small container is heat-sealed at at least one portion of a peripheral edge thereof,

the sealed portion being openable by external force,

a nonbonded portion of the small container inwardly of the sealed portion of the peripheral edge having a bonded portion bonded to the inner wall surfaces of the chamber.

7. (Amended) A multiple-chamber medical container according to claim 1, wherein the bonded portion of the small container comprises a plurality of bonded parts arranged with at least one nonbonded part positioned therebetween.

8. (Amended) A multiple-chamber medical container according to claim 7, wherein said at least one nonbonded part is provided in the vicinity of the center of the bonded portion.

9. (Amended) A multiple-chamber medical container according to claim 1 or 3, wherein the sheet material of the small container comprises a multilayer film and the small container is opened by delaminating the multilayer film.

10. A multiple-chamber medical container according to claim 9, wherein the sheet material of the small container comprises a multilayer film formed by laminating a plurality of resin layers having low miscibility with one another.

11. (Amended) A multiple-chamber medical container according to claim 1 or 3, wherein the sheet material of the

small container is at least partly heat-sealed, the sealed portion being openable by an external force.

12. (Amended) A multiple-chamber medical container according to claim 1 or 3, wherein the small container is disposed in at least one of the chambers to thereby accommodate the medicament in the chamber.

13. A multiple-chamber medical container according to claim 12, wherein the medicinal outlet portion is connected to the chamber having the small container disposed therein.

14. (Amended) A multiple-chamber medical container according to claim 1 or 3, wherein a discharge-control seal portion is further provided as an openable partition between the medicinal outlet portion and the chamber.

15. (Amended) A multiple-chamber medical container according to claim 1 or 3, wherein a medicament selected from among an antibiotic, anticancer drug, cardiotonic drug, vitamin and trace element is enclosed in the small container.

16. (Amended) A bag for enclosing therein at least one multiple-chamber medical container according to claims 1 or 3, wherein

the bonded portion of the small container is provided approximately in parallel to the partitioning seal portion, and

the medical container is folded along an edge of the bonded portion on one side thereof opposite to the partitioning seal portion before being placed into the bag.